General

Guideline Title

ACR Appropriateness Criteria® imaging after total knee arthroplasty.

Bibliographic Source(s)

Weissman BN, Shah N, Daffner RH, Bancroft L, Bennett DL, Blebea JS, Bruno MA, Fries IB, Hayes CW, Kransdorf MJ, Luchs JS, Morrison WB, Palestro CJ, Roberts CC, Stoller DW, Taljanovic MS, Tuite MJ, Ward RJ, Wise JN, Zoga AC, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness CriteriaÂ® imaging after total knee arthroplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 13 p. [95 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Weissman BN, Dalinka MK, Daffner RH, Jacobson JA, Morrison WB, Palmer WE, Resnik CS, Rubin DA, Schneider R, Schweitzer ME, Seeger LL, Steinbach LS, Haralson RH III, Expert Panel on Musculoskeletal Imaging. Imaging after total knee arthroplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 7 p.

The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Imaging after Total Knee Arthroplasty

Variant 1: Routine follow-up of asymptomatic patient with TKA.

Radiologic Procedure	Rating	Comments	RRL*
X-ray knee	9		
Fluoroscopy knee	1		
X-ray arthrography knee	1		

Radiologic Procedure	Rating	Comments	RRL*
CT knee without contrast	1		
MRI knee without contrast	1		O
US knee	1		O
Tc-99m bone scan knee	1		
In-111 WBC and sulfur colloid scan knee	1		
FDG-PET knee	1		
Ga-67 scan knee	1		
Aspiration knee	1		NS
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Pain after TKA: initial evaluation, suspect periprosthetic infection.

Radiologic Procedure	Rating	Comments	RRL*
X-ray knee	9	Both x-ray and joint aspiration are appropriate procedures at this time.	
Aspiration knee	9	Both x-ray and joint aspiration are appropriate procedures at this time.	NS
Fluoroscopy knee	1		
X-ray arthrography knee	1		
CT knee without contrast	1		
MRI knee without contrast	1		O
US knee	1		O
Tc-99m bone scan knee	1		
In-111 WBC and sulfur colloid scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Radiologic Procedure	Rating	Comments	RRL*
FDG-PET knee	1		
Ga-67 scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Pain after TKA: positive aspiration for infection. Next study following radiographs.

Radiologic Procedure	Rating	Comments	RRL*
CT knee with or without contrast	5		
MRI knee with or without contrast	5	See statement regarding contrast in text under "Anticipated Exceptions."	O
Fluoroscopy knee	1		
X-ray arthrography knee	1		
US knee	1		O
Tc-99m bone scan knee	1		
In-111 WBC and sulfur colloid scan	1		
FDG-PET knee	1		
Ga-67 scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Pain after TKA: suspect infection, joint aspiration culture(s) negative or inconclusive. Next study following radiographs.

Radiologic Procedure	Rating	Comments	RRL*
In-111 WBC and sulfur colloid scan knee	8		
CT knee with or without contrast	5		
MRI knee with or without contrast	5	See statement regarding contrast in text under "Anticipated Exceptions."	O
Tc-99m bone scan knee	4		
Fluoroscopy knee	1		
X-ray arthrography knee	1		
US knee	1		O
FDG-PET knee	1		
Ga-67 scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Pain after TKA: positive radiograph for loosening. Negative aspiration for infection.

Radiologic Procedure	Rating	Comments	RRL*
CT knee without contrast	5	To assess bone loss.	
MRI knee without contrast	4		O
Fluoroscopy knee	1		
X-ray arthrography knee	1		
US knee	1		O
Tc-99m bone scan knee	1		
In-111 WBC and sulfur colloid scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Radiologic Procedure	Rating	Comments	RRL*
FDG-PET knee	1		
Ga-67 scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Pain after TKA: negative radiograph for loosening. Low probability of infection.

Radiologic Procedure	Rating	Comments	RRL*
CT knee without contrast	8	Occult fracture, loosening or malposition.	
MRI knee without contrast	6		O
Tc-99m bone scan knee	5		
Fluoroscopy knee	1		
X-ray arthrography knee	1		
US knee	1		O
In-111 WBC and sulfur colloid scan knee	1		
FDG-PET knee	1		
Ga-67 scan knee	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Total knee arthroplasty (TKA) has become a more commonly performed procedure than total hip arthroplasty. In 2003 in the United States,

402,100 primary and 32,700 revision total knee arthroplasties were performed, and it has been estimated that by 2030, the annual demand for primary TKA will grow by 673% to 3.48 million. Patient satisfaction is greater than 90%, and there is a reported implant survival rate approaching 93% at 15 years and 83% at 20 years. Nonetheless, failures do occur, and their causes can be grouped as either extra-articular (e.g., bursitis, tendinitis, stress fracture, periprosthetic fracture) or intra-articular (including infection, instability, malalignment, aseptic loosening, prosthesis fracture, polyethylene wear, osteolysis, arthrofibrosis, soft-tissue impingement, and extensor mechanism problems such as patellar maltracking). One study reviewed the causes of failure of 212 consecutive revision total knee replacements. The most common causes of failure were polyethylene wear (25%), aseptic loosening (24.1%), instability (21.2%), infection (17.5%), arthrofibrosis (14.6%), malalignment or malposition (11.8%), and extensor mechanism deficiency (6.6%). Early failure (before 2 years) was due in 50% of cases to instability, malalignment, malposition, or failure of fixation. The most common cause of failure in the early group was infection (25.4%). Late failure was usually the result of wear, loosening, or instability.

Routine Imaging

Postoperative Radiographs

The timing of postoperative radiographs has been evaluated in an effort to decrease costs. Postoperative in-hospital radiographs are thought unnecessary if the surgery was uncomplicated. Baseline radiographs are suggested at the first outpatient visit (e.g., at 6 weeks). In-hospital baseline radiographs are less likely to be technically satisfactory than outpatient radiographs, but if they are satisfactory, routine repeat radiographs at the early follow-up visit are thought to be unnecessary.

The effectiveness of radiographs obtained upon admission to a rehabilitation facility following hip or knee arthroplasty has been studied. A retrospective review examined the charts of 209 patients admitted after total knee replacement and found that two patients (0.95%) had abnormal findings on radiographs. There was no change in the length of hospital stay or the medical intervention required in these patients, leading the authors to conclude that routine radiography upon admission to a rehabilitation facility after knee replacement surgery is not cost-effective.

Later follow-up is directed toward identifying any of the complications mentioned above, particularly loosening. Evaluation of serial radiographs is particularly helpful for determining subtle changes. Although follow-up radiographs are commonly performed, the frequency of assessment has not been standardized. A survey of 682 active members of the American Association of Hip and Knee Surgeons in 2003 found that 80% of responders recommended annual or every-other-year orthopedic and radiographic examinations and more frequent follow-up if there were signs of failure, prior revision or sepsis, or subnormal periprosthetic bone quality. The recommendation for follow-up every 1 or 2 years continued for the long term (>10 years).

Computed Tomography and Magnetic Resonance Imaging

Computed tomography (CT) and magnetic resonance imaging (MRI) were initially thought not to play a role in the assessment of joint prostheses due to image degradation by artifact. Newer techniques and instrumentation have been developed, however, that markedly improve assessment of patients with joint replacements. Routine use of these techniques for follow-up of asymptomatic patients has not been studied.

Complications

Identification of the cause of a painful TKA is important preoperatively since "…re-operation is unwise and frequently associated with suboptimal results" in cases of unexplained pain.

Loosening

In one series, polyethylene wear and aseptic loosening were the most common causes of TKA failure; loosening was a cause of revision in 34% of cases performed 2 years or more after implant insertion.

Radiographs are the standard examination for detecting loosening. One group of researchers defined loosening on radiographs as the presence of prosthetic fracture, cement fracture, periprosthetic fracture, or gross component migration. Assessment of radiolucent lines has been an important tool in defining fixation and therefore, conversely, loosening. Thin, incomplete, nonprogressive radiolucent lines are not uncommon in patients without clinical loosening. Loosening is suggested when 1) there is progressive widening of a lucent zone on follow-up examinations, 2) there is a >2 mm wide lucent zone at the cement bone interface or any lucency at the metal-cement or metal-bone interface, or 3) the lucent zone is extensive, especially if around the pegs or stem of a component. These lucent lines should be distinguished from more diffuse bone loss that occurs in areas of decreased stress ("stress shielding").

One study found radiographs to have a sensitivity of 77% and specificity of 90% for detecting femoral component loosening and a sensitivity of 83% and specificity of 72% for detecting tibial component loosening in comparison to findings at surgery.

Fluoroscopy may be useful to see lucent lines in profile that could be obscured on standard anterior-posterior (AP) radiographs or sometimes for demonstrating loosening in real time under manipulation.

Bone scintigraphy may be helpful in diagnosing loosening, especially when obtained many years after surgery. This delay in maximum utility is due to the observation that positive bone scans are noted in 20% of asymptomatic knees a year after surgery and in 12.5% of individuals 2 years postoperatively. Serial bone scans may be more helpful than a single examination. Generally, increased isotope uptake on the static scan but not on the blood pool scans is thought more likely due to loosening than to infection. Normal scans are most helpful, indicating that loosening or infection is unlikely. Evaluation of 80 bone scans in patients with symptomatic TKAs, where any study with even mildly increased activity on either blood pool or delayed images was classified as abnormal, found that the test distinguished abnormal patients (loosening or infection) from normal ones (sensitivity of 92.3%) but was unable to distinguish between these two abnormal conditions. If infection is excluded by other studies, loosening of the tibial component may be detected using quantitative analysis of bone scintigraphy with a sensitivity of 90% and specificity of 100%.

Arthrography (with subtraction technique) has been found to have poorer positive and negative predictive values than radiography for detecting loosening.

Infection

Infection is the most serious complication of joint arthroplasty and is reported in 0.8%-1.9 % of TKAs. The frequency of infection is increasing as the number of primary arthroplasties is increasing. Infection may be acute or delayed. Late infection has been defined as occurring at least 3 months post-surgery. In one series, infection was responsible for 25.4% of early revisions and 7.8% of revisions performed more than 2 years after the initial operation. *Staphylococcus epidermidis* and *Staphylococcus aureus* are the most common organisms associated with these infections. Low-grade or chronic infections may be more difficult to identify. One study noted that the diagnosis of infection was not obvious in 53% of knees prior to revision arthroplasty.

Clinical Features

Pain is the most common presenting symptom of infection; however, it is a nonspecific finding. Night pain or pain at rest is typical of infection, whereas pain on weight bearing is more consistent with mechanical loosening. Some authors suggest that infection be excluded in all patients with persistent pain more than 6 months following joint replacement. In acute infection, findings such as pain, swelling, warmth, erythema, and fever are common, whereas chronic infections may be manifested by pain alone. Thus, a knee may be infected without the presence of fever, chills, erythema, or swelling. Loosening may result from infection.

On June 18, 2010, the American Academy of Orthopaedic Surgeons (AAOS) published a guideline and evidence report on *The Diagnosis of Periprosthetic Joint Infections of the Hip and Knee*. The work group was of the opinion that testing strategies should be planned according to whether there is a higher or lower probability that a patient has a periprosthetic infection. Patients with a high probability of infection included patients with one or more symptoms and one or more risk factors (e.g., prior knee infection, superficial surgical site infection, operative time >2.5 hours, and immunosuppression) or a physical examination finding or early implant loosening/osteolysis as detected by x-ray.

Laboratory

Laboratory findings are often nonspecific. Peripheral leukocyte counts are not elevated in most patients with infected prostheses. Sedimentation rates are abnormal in patients with infection but this finding may also be seen in uninfected patients, limiting the value of the test. A retrospective review of 68 patients undergoing hip and knee revision surgery indicated that C-reactive protein (CRP) was significantly higher in patients with infection compared to those with loosening (sensitivity 79% for all prostheses), although a normal level did not exclude infection. CRP has a sensitivity of 73%-91% and a specificity of 81%-86% for the diagnosis of prosthetic knee infection when a cutoff of 13.5 mg/L or more is used. CRP generally returns to baseline values within 2 months after surgery. A large multicenter study found CRP and joint aspiration to be the most useful tools to diagnose infection. In an attempt to construct an algorithm for evaluating TKA infection, the presence of at least two positive tests for CRP (cutoff 0.93 mg/L), erythrocyte sedimentation rate (ESR) (cutoff 27 mm/h), and fibrinogen (cutoff 432 mg/dl) led to accurate results for the diagnosis of infection (sensitivity 93%, specificity 100%, and accuracy 97%). The AAOS guidelines recommend the use of ESR and CRP testing for patients being assessed for periprosthetic joint infection noting that when both ESR and CRP are negative, infection is unlikely. Positive results warrant further evaluation.

Aspiration

Knee joint aspiration has been found to be extremely useful in diagnosing joint infection after TKA. Total and differential cell count and culture should be obtained. One study found a sensitivity, specificity, and accuracy of 100% for aspiration in a series of 43 knees with pain, instability, loosening, or suspected infection undergoing surgical revision. In contrast, radiographic findings did not separate infected from noninfected patients. Another study found joint aspiration to be 100% specific and 75% sensitive for diagnosing infection and to be the best test for diagnosing infection

in a group of total hip and knee replacement patients. A third study found that early aspiration led to a significant reduction in the duration of treatment and a better outcome. In 16% of patients, more than 3 aspirations were necessary to obtain a positive culture. Another group of researchers noted that in contrast to aspiration of total hip replacements where false positive results are more common, aspirations of knee joints are more often falsely negative. This was thought to most often result from antibiotic treatment. At least 2 weeks off antibiotics is recommended before the aspiration is performed (with careful clinical monitoring for sepsis), but as long as a month may be necessary for cultures of aspirated fluid to become positive. Therefore, a weekly repeat aspiration is recommended if the first aspiration is negative and clinical suspicion for infection remains high. Even with a negative preoperative aspiration, intra-operative tissue may indicate infection. Another group of researchers, after literature review and a multicenter trial, advocated CRP and joint aspiration as the best tools for diagnosing prosthetic joint infection. When CRP level is >10 mg/L, repeat joint aspiration or biopsy is suggested. One study also found the combination of ESR and CRP to be a good screening tool for infection with only one infected knee having negative results on both tests. The authors suggest preoperative aspiration if the ESR or CRP is elevated or if clinical suspicion is high, combined with intra-operative frozen section analysis of the periprosthetic synovial tissue. The AAOS recommends joint aspiration of patients being assessed for periprosthetic knee infections who have abnormal ESR *and/or* CRP results. The opinion of the group was that repeat knee aspiration should be performed when there is a discrepancy between the probability of periprosthetic joint infection and the initial aspiration culture result.

Radiographs

One study found radiographs not to be helpful since loosening, periostitis, focal osteolysis, and radiolucent lines were seen in both infected and uninfected knees. Most importantly, infection may be present with a "normal" radiographic appearance.

Bone Scan

It is usually stated that bone scintigraphy is useful for excluding infection but of limited value in detecting it; thus sensitivity is higher than specificity. Triple-phase scintigraphy does not improve the accuracy of the test.

Increased uptake may persist on bone scan even at 2 years after surgery. Infection is more likely than aseptic loosening if there is increased uptake on both blood pool and delayed images. Analysis of 80 bone scans in patients with postoperative pain found that no patient with infection had a negative scan. Patients with abnormal scans should be further assessed. When the equipment or expertise is not available for white blood cell (WBC) scanning, three-phase bone scanning may be valuable, even though its accuracy is lower than that of the WBC or positron emission tomography (PET) scan.

Sequential Bone/Ga-67 Scanning

Gallium-67 accumulates in areas of septic or aseptic inflammation, in bone marrow, and in regions of increased bone mineral turnover. Image interpretation usually involves comparison of the isotope uptake on the gallium scan with isotope intensity and distribution on bone scan. Although limited statistics are available for knee imaging specifically, the ability to differentiate infected from uninfected prostheses using these scans appears to be limited. Gallium scanning has largely been replaced by indium-labeled leukocyte imaging for diagnosing prosthetic joint infection.

Labeled Leukocyte Scintigraphy

Leukocyte scanning using indium-111 was introduced in the 1980s. Leukocytes may be labeled in vitro with indium-111 oxine or technetium-99m exametazime. Labeling leukocytes in vitro requires that the patient's venous blood sample be drawn and the white blood cells (WBCs) isolated and labeled. The labeled WBCs then are injected intravenously. Imaging usually is performed 24 hours later. Comparison of activity on the labeled leukocyte image to activity on the bone scan has been advocated. A positive study for infection generally requires increased activity on the labeled leukocyte study, either in a different distribution (an "incongruent" scan) or in greater intensity than on the bone scan. A small sample of indium scans in uncomplicated postoperative TKA patients has shown that inflammation can persist around the operative site.

One study reported an accuracy of 75% for diagnosing prosthetic knee infection with combined bone-marrow-labeled leukocyte imaging. Another study evaluated bone and indium-111-labeled leukocyte scans in patients with loose or painful knee prostheses and found a sensitivity of 88%, specificity of 78%, positive predictive value (PPV) 75% and negative predictive value (NPV) of 90% for infection. The examination was not recommended as routine because of the expense, complexity and limited sensitivity, specificity, PPV, and accuracy. In equivocal cases, and when an experienced musculoskeletal pathologist is not available to interpret an intra-operative frozen section, these authors noted that a negative indium scan may be helpful to suggest the absence of infection.

A group of researchers reported a multicenter trial of various methods for diagnosing hip and knee infections. Scans using tagged white cells or radiolabeled immunoglobulin demonstrated a sensitivity of 74% and specificity of 76% for diagnosing infection. A literature review indicates sensitivities of 40%-96% and specificities of 76%-100% for WBC scans of joint prostheses. These studies were, therefore, (as noted above) not recommended as routine for differentiating mechanical failure from occult infection in painful loose total knee prostheses. One study applied single

photon emission tomography/computed tomography (SPECT/CT) using a hybrid camera to conventional Tc-99m-HMPAO-labeled leukocyte scintigraphy in patients with suspected infection. SPECT/CT was able to differentiate soft-tissue involvement from bone involvement. It may eliminate the necessity for a correlative bone scan.

Leukocyte/Bone Marrow Scanning

Labeled leukocyte imaging may lead to a high false positive rate because leukocytes accumulate in bone marrow as well as in infection and it is not always possible to differentiate between the two. The addition of Tc-99m-labeled sulfur colloid bone marrow scanning has been investigated to reduce this confusion. One study reported that combined leukocyte/marrow imaging was 95% accurate for diagnosing prosthetic knee infection and was superior to bone scintigraphy alone and in combination with labeled leukocyte imaging. Another study, however, found that low sensitivity and the potential for false negative results made this combination of scans of limited utility for diagnosing prosthetic infection, and therefore it is no longer used in their institution. In that group of 22 total knee prostheses evaluated and later operated upon, there was a sensitivity of 66%, specificity of 100%, PPV of 100%, NPV of 88%, and accuracy of 91%. The addition of blood pool and flow scans was investigated to determine if hyperemia led to a match of bone-marrow-labeled leukocyte uptake (and therefore, a falsely negative scan). These additional scans decreased the number of false negative findings (sensitivity of 83%, specificity of 94%, PPV of 83%, NPV of 94%). Overall, however, the performance of the labeled leukocyte marrow scan protocol was again thought to be of limited clinical utility. A group of researchers found the combination of indium-111-labeled leukocyte/Tc-99m-labeled sulfur colloid marrow scanning to be the gold standard for diagnosing periprosthetic infection. These authors found the combination of labeled WBC and marrow scanning to be 100% sensitive and 100% specific for diagnosing infection in total knee arthroplasties. Semiquantitative assessment of WBC scans, using a combination of early and delayed imaging as a substitute for bone marrow imaging, produced >90% sensitivity and specificity in one series.

A study of a small series of total knee arthroplasties using indium-111 IgG (immunoglobulin G) found the sensitivity of this agent for infection to be high but its specificity low (sensitivity 100%, specificity of 50%). Indium-111-labeled immunoglobulin is not available in the United States.

FDG-PET

PET with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PET) imaging may be useful for detecting infection after joint replacement. One study reported that elevated glycolytic activity causes inflammatory cells such as neutrophils and activated macrophages to be FDG avid at sites of inflammation and infection.

This examination is much faster (a few hours) and less expensive than combined bone, marrow, and in-vitro labeled WBC scintigraphy. It requires a single injection and no handling of blood samples. Negatives include the higher cost and more limited availability. Some periprosthetic uptake may occur due to marrow activity, and adding marrow scanning can increase specificity.

Efficacy for Infection. A study of 36 painful knee prostheses examined using FDG-PET scanning showed identification of 10 of 11 infected cases but false positive results in 7 cases (sensitivity of 90.9%, specificity of 72%, and accuracy of 77.8% for detecting infection). This was lower accuracy than for assessment of hip prostheses. The cause for the high number of false positives was not known. In another series, the use of FDG-PET scanning combined with bone scanning showed no advantage over hexa-methyl propylene-amine-oxime (HMPAO)-labeled WBC scan and bone scanning. Comparison of coincidence detection using FDG scanning with indium-111-labeled leukocyte/Tc-99m-labeled sulfur colloid marrow imaging showed that the FDG imaging was less accurate than the leukocyte/marrow imaging and could not replace that combination of tests. Another study reported that, by analyzing intensity and periprosthetic uptake patterns on FDG-PET images, accurate differentiation among aseptic loosening, synovitis, and infection is possible. A meta-analysis reported that the specificity of FDG-PET for diagnosing infection was significantly lower for knee (74.8%) than for hip (89.8%) prostheses.

Aseptic Conditions. Synovitis and aseptic loosening (in hip prostheses) may cause increased FDG uptake. One study found diffuse synovial and focal extrasynovial FDG-PET uptake in patients with component malrotation. It concluded that this test is noncontributory in individual patients with persistent pain. Another study examined 14 patients with painful TKAs to detect early aseptic loosening. Overall accuracy was 71% (sensitivity 100%, specificity 56%). A third study in a series of both hip and knee prostheses found that a negative PET scan excluded infection (100% sensitivity). If the scan is positive, differentiation between wear and infection was not possible. The utility of PET/CT for evaluating prostheses has not been investigated. In the United States, FDG-PET is not approved for imaging inflammation and infection.

Anti-granulocyte Scintigraphy

Radiolabeled monoclonal antibodies or antibody fragments that directly target leukocyte antigens or receptors are used to assess the concentration of granulocytes in the tissue around a prosthesis. Meta-analysis of 13 studies of joint prostheses (522 implants) using antigranulocyte scintigraphy (AGS) with monoclonal antibodies has shown the independent random effects summary estimates of sensitivity to be 83% and specificity to be 80%. A weighted positive likelihood ratio of 3.99 and a weighted negative likelihood ratio of 0.22 were determined. There was no statistically significant difference between these findings and the performance of AGS for total hip or knee implants. The authors concluded that these tests

offered "reasonably high discriminating ability" for infected as opposed to noninfected prostheses. A group of researchers, in a study of 26 TKAs (24 infected), found that using 99mTc-Fab' yielded excellent results in severe infections (100% sensitivity and specificity) but had limited efficacy in mild to moderate infections. Quantitative evaluation using early and late imaging improved results in patients with these milder infections. None of these agents are available, even on an investigational basis, in the United States.

99mTc-labeled Interleukin 8 Scintigraphy

Interleukin 8 is a chemotactic cytokine that binds to receptors expressed on neutrophils. Preliminary study has shown this to be a safe method for detecting focal infection as early as 4 hours after injection of the agent. This agent is not available, even on an investigational basis, in the United States.

The AAOS guidelines indicate that various nuclear imaging tests are an option in patients in whom the diagnosis of periprosthetic joint infection has not been established and who are not scheduled for reoperation.

CT and MRI

The role of CT and MRI has not been definitively elucidated for evaluation of periprosthetic infections, and more study is needed. One study found that infected synovium has hyperintense laminar appearance (different from the appearance of particle disease). They noted that in selected cases, MRI may be helpful in detecting extracapsular spread of infection and abscess formation.

Wear

Polyethylene Thickness

The polyethylene articular surface of a total knee prosthesis may undergo true wear, deformation, and creep that lead to a decrease in the thickness of the polyethylene; these conditions may be clinically referred to as "wear." Several methods have been used to study the thickness of the polyethylene and thus the extent of wear.

One study examined single-leg standing frontal radiographs of the knees for assessing of polyethylene thickness. Two types of measurement were made: 1) minimum distance from the metallic femoral condyle to the metal backing baseplate, and 2) minimum distance from the metallic femoral condyle to a line through the top surface of the baseplate at its widest dimension. The latter method proved more accurate and less affected by tilting of the tibial component. Overall, 87% of measurements using the second method were within 1 mm of the known implant thickness (accuracy roughly +/- 1 mm initially). However, accuracy decreased for evaluating polyethylene thickness in patients with wear requiring revision.

Fluoroscopy has been used to align radiographs perpendicular to the joint surface in an effort to compensate for any tilt of the tibial component. This technique allows measurement of the thickness of the polyethylene liner so that decreases in liner thickness (indicating wear) can be detected. Correction for magnification is made using the known diameter of a portion of the tibial component. In vivo assessment has shown the repeatability (precision) of these measurements to be 0.2 mm with a 99% confidence level. The major source of variation is angulation of the tube in the craniocaudal direction; a 0.33 mm (6.5%) change in mean insert thickness is seen per degree of angulation. One study noted that the magnification error cannot be reduced to $\leq$1 mm using fluoroscopy.

Varus/valgus stress has been added to the fluoroscopic examination to improve evaluation of polyethylene thickness. The coefficient of variation for repeat examination was 3.4%.

Ultrasonography (US) is under investigation for evaluating the thickness of polyethylene liners, but is not in general use for this purpose. Cadaver studies show US measurements to be accurate to 0.5 mm with a 95% confidence interval in comparison to caliper measurements and in-vivo studies have shown high correlation between radiographic and sonographic measurements.

Granulomas

Radiographs. Focal osteolysis due to wear particles may be visible on radiographs as lucent lesions. In one study, focal osteolysis was defined as an isolated area of lucency measuring at least 3 mm in diameter. It may be difficult to differentiate these lytic defects from more poorly defined lucencies seen in stress shielding (osteoporosis).

Routine radiographic surveillance has been suggested even in asymptomatic patients to detect granulomas. For example, the Implant Wear Symposium 2007 Clinical Work Group suggested that "follow-up radiographs be obtained in the early postoperative period and at 1, 5, and at 10 years postoperatively and then every 1 to 5 years, depending on radiographic findings of osteolysis and its progression." Oblique posterior femoral condylar radiographs have been recommended for evaluating the posterior femoral condyles after TKA. This method was thought to be especially helpful when a posterior stabilized prosthesis is in place.

Unfortunately, radiographs have been shown to be insensitive for detecting and characterizing granulomas around total knee prostheses. In one study, only 17% of 48 lesions visible by CT were detected on radiographs, and detected lesions were eight times larger than radiographically occult lesions. Similarly, MRI with techniques to decrease metal artifact can detect osteolysis even around the femoral component that is not visible on radiographs. An MRI investigation of 11 TKAs suspected of osteolysis on radiographs (and subsequently confirmed by surgery) found 10 with proven osteolysis confirmed at MRI and surgery, additional osteolytic lesions on MRI in 5 cases, and greater extent of lesions in 9 cases on MRI than were identified on radiographs.

CT. Use of modified imaging techniques may improve CT and MRI quality for evaluating the postoperative orthopedic patient. CT can be used to detect osteolysis and to determine total volume of osteolytic lesions. CT is recommended by a group of investigators in patients with painful knee prostheses with normal or equivocal radiographs and increased uptake on all three phases of a bone scan to look for osteolysis. Another group of researchers recommend multidetector CT in cases where osteolysis is expected, such as when there is aseptic loosening and gross polyethylene wear.

CT examination may also be useful in patients with painful knee prostheses and equivocal radiographs, particularly for:

- Loosening: to show the extent and width of lucent zones that may be less apparent on radiographs.
- Assessing rotational alignment of components.
- Detecting subtle or occult periprosthetic fractures.

One study found multidetector CT (MDCT) imaging to have limitations in the assessment of bone marrow and soft tissues, for which MRI remains the modality of choice.

CT arthrography may be useful in documenting large displaced polyethylene fragments. In one case, CT arthrography allowed identification of the nonopaque polyethylene fragment of the tip of a posterior stabilized prosthesis.

MRI. Improved pulse sequences and techniques have facilitated the evaluation of the periprosthetic soft tissues and bone, allowing demonstration of focal osteolysis and inflammatory synovitis, as well as ligament, tendon, and nerve abnormalities. Synovial changes due to particle disease may be seen before osteolytic lesions are apparent.

US. In experienced hands, US can be used to evaluate the polyethylene liner, tendons, and synovitis and to guide joint aspiration.

Patellar Complications

Patellar complications include subluxation, dislocation, fracture, component loosening or wear, impingement, and osteonecrosis. In a series of 1,272 consecutive radiographic examinations (and US when obtained) patellar complications were found in 3.6%. Radiographs are usually satisfactory for assessment and are helpful in guiding treatment. A group of researchers recommend a weight-bearing axial radiograph to better assess patellofemoral kinematics.

Patellar fractures occur in up to 5.2% of patients, usually within the first few postoperative years. Most are not associated with prior injury, and many are asymptomatic, highlighting the importance of radiography for their identification. Transverse fractures are thought to be associated with patellar maltracking, while vertical fractures often occur through a fixation hole.

Component Rotation

Malposition of femoral and tibial components may affect patellar alignment. Although axial radiographs may be used to determine axial rotation of the femoral component, CT is most commonly used for this purpose. MRI may also allow this evaluation. It has been documented that excessive combined internal rotation of tibial and femoral components is associated with patellar complications. Furthermore, one study found the amount of excessive combined internal rotation to be directly proportional to the severity of patellofemoral complications.

The rotation of tibial and femoral components is most often evaluated using internal anatomical landmarks for reference (see below). Femoral component rotation may be assessed with relation to the transepicondylar axis, the Whiteside line, or the posterior femoral condyles. One group of researchers constructs the transepicondylar axis from the lateral epicondyle to the trough in the medial epicondyle. Unfortunately, this trough is only visible in a little more than half of patients, and therefore measurement to the peak of the lateral epicondyle has also been used (called the condylar twist angle). According to another group of researchers the femoral component should be parallel to the transepicondylar axis, and the tibial component should be in about 18 degrees of internal rotation with relation to the tibial tubercle.

Another research group studied the accuracy of a CT method for evaluating femoral and tibial component rotation and found the coefficient of variation between CT and digital imaging of cadaver specimens to average 0.87.

Other Complications

Quadriceps or patellar tendon tears may occur, and US or MRI may be used for evaluation. Arthrofibrosis has been evaluated using US or MRI. Periprosthetic fractures are generally assessed on radiographs. Radiographically occult fracture may be detected on MRI or on CT.

Summary

- Radiographs are the standard method for evaluating loosening or infection but are limited in their sensitivity and specificity.
- Bone scans may be positive in asymptomatic patients even 2 years postoperatively and are, therefore, most helpful when evaluating patients many years after surgery.
- Joint aspiration is an effective method of diagnosing infection after total knee arthroplasty if antibiotic treatment is withheld for at least 2 weeks before. Repeat aspirations may be necessary.
- In questionable cases, the combination of leukocyte and bone marrow imaging may be helpful.
- CT and MRI appear to be more sensitive than radiographs for granuloma detection and assessment.
- CT is helpful for measuring component rotational alignment.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field.

Abbreviations

- CT, computed tomography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography
- Ga, gallium
- In-111 WBC, indium-111-labeled white blood cells
- MRI, magnetic resonance imaging
- NS, not specified
- Tc, technetium
- TKA, total knee arthroplasty
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☐	<0.1 mSv	<0.03 mSv
☐☐	0.1-1 mSv	0.03-0.3 mSv
☐☐☐	1-10 mSv	0.3-3 mSv
☐☐☐☐	10-30 mSv	3-10 mSv
☐☐☐☐☐	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as NS (not specified).		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Complications after total knee arthroplasty (TKA), including infection, component loosening, and component wear

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Internal Medicine

Nuclear Medicine

Orthopedic Surgery

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for evaluation of complications after total knee arthroplasty

Target Population

Patients with suspected complications after total knee arthroplasty

Interventions and Practices Considered

1. X-ray, knee
    - Fluoroscopy
    - Arthrography
2. Computed tomography (CT), knee, with or without contrast
3. Magnetic resonance imaging (MRI), knee, with or without contrast
4. Nuclear medicine

- Technetium (Tc)-99m bone scan, knee
- Gallium (Ga)-67 scan, knee
- Indium (In)-111-labeled white blood cell (WBC) and sulfur colloid scan, knee

5. Fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography (FDG-PET), knee
6. Aspiration, knee
7. Ultrasound (US), knee

Major Outcomes Considered

Utility of radiologic examinations in differential diagnosis

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the American College of Radiology (ACR) Appropriateness Criteria® Evidence Table Development document (see "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of patients after total knee arthroplasty

Potential Harms

- In contrast to aspiration of total hip replacements where false positive results are more common, aspirations of knee joints are more often falsely negative.
- Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) can render false positive results
- Labeled leukocyte imaging may lead to a high false positive rate because leukocytes accumulate in bone marrow as well as in infection and it is not always possible to differentiate between the two.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible

benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Weissman BN, Shah N, Daffner RH, Bancroft L, Bennett DL, Blebea JS, Bruno MA, Fries IB, Hayes CW, Kransdorf MJ, Luchs JS, Morrison WB, Palestro CJ, Roberts CC, Stoller DW, Taljanovic MS, Tuite MJ, Ward RJ, Wise JN, Zoga AC, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness CriteriaÂ® imaging after total knee arthroplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 13 p. [95 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1995 (revised 2011)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Musculoskeletal Imaging

Composition of Group That Authored the Guideline

Panel Members: Barbara N. Weissman, MD; Nehal Shah, MD; Richard H. Daffner, MD; Laura Bancroft, MD; D. Lee Bennett, MD, MA; Judy S. Blebea, MD; Michael A. Bruno, MD; Ian Blair Fries, MD; Curtis W. Hayes, MD; Mark J. Kransdorf, MD; Jonathan S. Luchs, MD; William B. Morrison, MD; Christopher J. Palestro, MD; Catherine C. Roberts, MD; David W. Stoller, MD; Mihra S. Taljanovic, MD; Michael J. Tuite, MD; Robert J. Ward, MD; James N. Wise, MD; Adam C. Zoga

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Weissman BN, Dalinka MK, Daffner RH, Jacobson JA, Morrison WB, Palmer WE, Resnik CS, Rubin DA, Schneider R, Schweitzer ME, Seeger LL, Steinbach LS, Haralson RH III, Expert Panel on Musculoskeletal Imaging. Imaging after total knee arthroplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 7 p.

The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site .
- ACR Appropriateness Criteria® Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® imaging after total knee arthroplasty. Evidence table. Reston (VA): American College of Radiology; 2011. 32 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 25, 2007. This NGC summary was updated by ECRI Institute on July 7, 2011.

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